REMARKS

This is a full and timely response to the Office Action mailed May 5, 2004, submitted concurrently with a one month extension of time to extend the due date for response to September 5, 2004.

By this Amendment, claims 1 and 2 have been amended in light of the telephone interview with the Examiner on August 25, 2004. Support for the claim amendments can be found variously throughout the specification, see for example, pages 2-3 and 8. Claims 1-11 are pending in this application.

Applicant wishes to thank the Examiners for their consideration and helpful comments during the interview.

In view of this Amendment, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 1, 3-9 and 11 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ivanov et al. (U.S. Patent 6,183,998). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, the cited reference must teach or suggest all of the claim limitations (see §2142 of the Manual of Patent Examining Procedure). Here, in this case, Ivanov et al. fail to teach or suggest the limitation "*wherein said nucleic acid inclusion body or said living body-derived sample **itself** is added to the amplification reaction solution **without extracting and purifying said nucleic acid from said nucleic acid inclusion body***".

The term "*itself*" is specifically defined on page 8, line 16, to page 9, line 1, of the specification. It states that

> *". . . the term "itself" means that no special pretreatment is required. In the concrete, no following pretreatment is required; the nucleic acid inclusion body is decomposed using an enzyme, a surfactant, a chaotropic agent, or the like, and then nucleic acids are extracted from the decomposed product of the nucleic acid inclusion body using phenol, phenol/chloroform or the like. Further, pretreatment using an ion-exchange resin, a glass filter, glass beads, a reagent having an effect of agglutinating proteins, or the like is not required in the step of the nucleic acid extraction"*

In other words, the present invention is directed to a method for synthesis of nucleic acids to directly amplify an intended nucleic acid in a nucleic acid inclusion body (such as a cell, fungus, bacterium, or virus) of a living body-derived sample "***without extracting and purifying the nucleic acid from the nucleic acid inclusion body***. As the above definition discloses and the claims recite, the nucleic acid inclusion body from the living body-derived sample or the living body-derived sample **itself** is added to the amplification reaction solution and directly amplified. No extraction and purification pretreatment step of the nucleic acid is required.

In contrast, Ivanov et al. teach the extraction and purification of nucleic acid prior to amplification. In the examples of Ivanov et al. (see examples 7 and 8, columns 11-13, and example 15, columns 16-18), Ivanov et al. clearly disclose that human genomic DNA from human whole blood and RNA from HeLa cells are extracted and purified using commercial kits (QIAamp® Blood Kit and RNasy® Maxi Kit from Qiagen).

Thus, since Ivenov et al. fail to teach or suggest all the claim limitations, this rejection cannot be sustained and should be withdrawn.

Claims 10 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ivanov et al. (U.S. Patent 6,183,998) in view of Yamada et al. (U.S. Patent 5,369,096) or Kelly et al. (U.S. Patent 4,978,757) or Holliger et al. (U.S. Patent 4,820,309) or Ukachi et al. (U.S. Patent 4,683,280) or Endo et al. (U.S. Patent 4,368,314) or Taniguchi et al. (U.S. Patent 6,054,501). Applicant respectfully traverses this rejection. Since the deficiency in Ivanov et al. ("*wherein said nucleic acid inclusion body or said living body-derived sample itself is added to the amplification reaction solution without extracting and purifying said nucleic acid from said nucleic acid inclusion body*" or, in other words, *directly amplifying the intended nucleic acid in a nucleic acid inclusion body of a living body-derived sample without purifying and extracting the nucleic acid*) is not cured by the teaching and suggestions of the other cited references, this rejection cannot be sustained for the same reasons as noted above, and should be withdrawn.

Claim 2 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ivanov et al. (U.S. Patent 6,183,998) in view of Sandhu et al. (U.S. Patent 5,707,802). Applicant respectfully traverses this rejection for the same reasons as set forth above.

As already noted by the Examiner on page 9 of the Office Action, in Sandhu et al. a loopful of fungal culture was scraped off a culture plate using a sterile inoculation loop and

added to one milliliter of sterile water in a 1.5 ml microcentrifuge tube. This tube was then ***placed in a boiling water bath for 20 minutes in order to lyse the fungus and release DNA of the cells***. In other words, the sample in Sandhu et al. undergoes a pretreatment process of extracting (i.e. releasing) the nucleic acid from the fungus.

Thus, since Ivenov et al. and Sandhu et al., in combination, fail to teach or suggest all the claim limitations, this rejection cannot be sustained and should be withdrawn.

Rejection under 35 U.S.C. §112

Claims 1-11 are rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Applicant respectfully traverses this rejection.

However, in order to expedite prosecution, Applicant has amended claim 1 to address the Examiner's concerns. Specifically, claim 1 has been amended to replace the term *"a cellular or intracellular level body comprising nucleic acids"* with *"a nucleic acid inclusion body from a living body-derived sample, or the living body-derived sample itself comprising said nucleic acid inclusion body"* which the Examiner has indicated during the telephone interview to be acceptable based on the teachings on pages 2 and 8 of the specification.

Thus, in light of this amendment, withdrawal of this rejection is respectfully requested.

CONCLUSION

For the foregoing reasons, all the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

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Respectfully submitted,

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